WORK PLAN AND METHODOLOGY

1. Review of available literatures
    a. Journals and books shall be reviewed for articles on strategies and applications of bioanalytical method development and validation.
2. Selection of drugs
    a. Drugs from different therapeutic categories shall be selected.
    b. Drugs which require faster and better- performing bioanalytical methods shall be selected.
3. Database search for reported methods for the selected drugs.
    a. Exhaustive search shall be done in journals for available methods for estimation of selected drugs.
    b. The shortcomings and scope for further improvement in these methods shall be noted.
4. Procurement of the drug
    a. The drug shall be procured along with its certificate of analysis stating its identification, purity and physicochemical properties like solubility.
5. Instrumental method development
    a. Instrumental work shall comprise of development of separation and detection methods
    b. The drug to be used as reference standard shall be identified by mass spectrometry.
    c. A suitable internal standard shall be selected and procured.
    d. The mass parameters for the drug and internal standard shall be tuned and the transitions for quantification shall be optimized
    e. Optimum chromatographic separation conditions shall be developed by selecting the right column, mobile phase and other parameters.
6. Sample preparation method development
    a. The drug of interest shall be extracted from the biological mileu by separating it from the other interfering compounds present in the matrix.
    b. The chemistry, pKa and related physicochemical properties of the drug shall be understood by referring the collected literature of the drug.
    c. The following techniques shall be used alone or in combination for obtaining maximum recovery of drug from the biological matrix with minimal matrix effect:
    - Solid phase extraction
    - Protein precipitation using standard solvents
    - Protein precipitation using phospholipid removal cartridges
    - Liquid liquid extraction
    d. The ideal sample extraction technique shall be selected for each drug.

7. Validation of the developed bioanalytical method
    a. The method shall be validated as per FDA guidelines for the following parameters:
    - Precision and Accuracy
    - Selectivity and Matrix effect
    - Linearity
    - Sensitivity(LLOQ)
    - Recovery
    - Stability under different conditions of storage and handling